RECEIVED AF

FEB 14 2002

1652

Please type a plus sign (+) inside this box → [+]

PTO/SB/21 (08-00)

Approval for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

TECH CENTER 1600/2900

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

OIPE JC14

FEB 06 2002

PATENT & TRADEMARK OFFICE

TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission	15

Application Number	09/707,121
Filing Date	Nov 6, 2000
First Named Inventor	Mathur, Brian
Group Art Unit	1652
Examiner Name	Y. Pak
Attorney Docket Number	LEX-0083-USA

ENCLOSURES *(check all that apply)*

- ☐ Fee Transmittal Form
  - ☐ Fee Attached
- ☐ Amendment / Reply
  - ☒ After Final
  - ☐ Affidavits/declaration(s)
- ☐ Extension of Time Request
- ☐ Express Abandonment Request
- ☐ Information Disclosure Statement
- ☐ Certified Copy of Priority Document(s)
- ☐ Response to Missing Parts/ Incomplete Application
  - ☐ Response to Missing Parts under 37 CFR 1.52 or 1.53
- ☐ Assignment Papers *(for an Application)*
- ☐ Drawing(s)
- ☐ Licensing-related Papers
- ☐ Petition
- ☐ Petition to Convert to a Provisional Application
- ☐ Power of Attorney, Revocation Change of Correspondence Address
- ☐ Terminal Disclaimer
- ☐ Request for Refund
- ☐ CD, Number of CD(s) _____
- ☐ After Allowance Communication to Group
- ☐ Appeal Communication to Board of Appeals and Interferences
- ☐ Appeal Communication to Group *(Appeal Notice, Brief, Reply Brief)*
- ☐ Proprietary Information
- ☐ Status Letter
- ☒ Other Enclosure(s) *(please identify below):*
  return postcard

Remarks: 1 set of Declarations & Powers of Attorney/ 2 pages total

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm *or* Individual name	Lance K. Ishimoto Reg. No. 41,866 Lexicon Genetics Incorporated
Signature	Lance Ishimoto by Peter G Sf Reg No 40162
Date	January 11, 2002

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, Washington, D.C. 20231 on this date: January 11, 2002

Typed or printed name	Nancy Stacey		
Signature	Nancy Stacey	Date	January 11, 2002

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: Mathur, et al.

Serial No.: 09/707,121 Group Art Unit: 1652

Filed: November 6, 2000 Examiner: Y. Pak

For: NOVEL HUMAN KINASE PROTEIN AND POLYNUCLEOTIDES ENCODING THE SAME

Attorney Docket No.: LEX-0083-USA

11/B
(3q)
2/19/02
(NE)

AMENDMENTS AND RESPONSE UNDER 37 C.F.R. § 1.116

Commissioner for Patents
Washington, D.C. 20231

Sir:

The Applicants acknowledge the receipt of the Office Action mailed on December 13, 2001 (Paper No. 10), which has been carefully reviewed and studied. The Applicants respectfully submit the following amendments to the above-identified application and respectfully request reconsideration of the application in view of the following amendments and remarks. In order to facilitate the Examiner's evaluation of the application, Applicants have attempted to address the rejections in Paper No. 10 in the same order in which they were originally raised. Applicants believe that this response is filed in a timely manner and that no additional fee is due for the extension of time in connection with this response.

However, the Commissioner is authorized to charge any underpayment or credit any overpayment to Deposit Account No. 50-0892.

AMENDMENTS

A marked up version of the amended claims are attached as Exhibit A. A clean copy of all of the pending claims are attached as Exhibit B.

Please cancel Claim 1, without prejudice and without disclaimer solely in order to more rapidly progress the present case to allowance.

I. Status of Claims

Claims 1-4 are pending in the instant application. With this amendment Claim 1 is cancelled. For the PTO's convenience, a marked up version of the amended Claims are attached as Exhibit A. A clean copy of pending Claims 2-4 are attached hereto as Exhibit B.

RESPONSE

II. Rejection of Claim 4 Under 35 U.S.C. § 101

Claim 4 stands rejected under 35 U.S.C. section 101, as being allegedly not supported by a specific and substantial utility or a well-established utility. The Action alleges that Claim 4 is drawn to poly nucleotides encoding proteins of unidentified function. Applicants respectfully traverse.

As set forth by the Federal Circuit, "(t)he threshold of utility is not high: An invention is 'useful' under section 101 if it is capable of providing some identifiable benefit." *Juicy Whip Inc. v. Orange Bang Inc.*, 51 USPQ2d 1700 (Fed. Cir. 1999) (citing *Brenner v. Manson*, 383 U.S. 519, 534 (1966)). Additionally, the Federal Circuit has stated that "(t)o violate § 101 the claimed device must be totally incapable of achieving a useful result." *Brooktree Corp. v. Advanced Micro Devices, Inc.*, 977 F.2d 1555, 1571 (Fed. Cir. 1992), emphasis added. *Cross v. Iizuka* (224 USPQ 739 (Fed. Cir. 1985); "*Cross*") states "any utility of the claimed compounds is sufficient to satisfy 35 U.S.C. § 101". *Cross* at 748, emphasis added. Indeed, the Federal Circuit recently emphatically confirmed that "anything under the sun that is made by man" is patentable *(State Street Bank & Trust Co. v. Signature Financial Group Inc.*, 47 USPQ2d 1596, 1600 (Fed. Cir. 1998), citing the U.S. Supreme Court's decision in *Diamond vs. Chakrabarty*, 206 USPQ 193 (S.Ct. 1980)).

In *In re Brana,* (34 USPQ2d 1436 (Fed. Cir. 1995), "*Brana*"), the Federal Circuit admonished the P.T.O. for confusing "the requirements under the law for obtaining a patent with the requirements for obtaining government approval to market a particular drug for human consumption". *Brana* at 1442. The Federal Circuit went on to state:

> At issue in this case is an important question of the legal constraints on patent office examination practice and policy. The question is, with regard to pharmaceutical inventions, what must the applicant provide regarding the practical utility or usefulness of the invention for which patent protection is sought. This is not a new issue; it is one which we would have thought had been settled by case law years ago.

Brana at 1439, emphasis added. The choice of the phrase "utility or usefulness" in the foregoing quotation is highly pertinent. The Federal Circuit is evidently using "utility" to refer to rejections under 35 U.S.C. § 101, and is using "usefulness" to refer to rejections under 35 U.S.C. § 112, first paragraph. This is made evident in the continuing text in *Brana*, which explains the correlation between 35 U.S.C. §§ 101 and 112, first paragraph. The Federal Circuit concluded:

> FDA approval, however, is not a prerequisite for finding a compound useful within the meaning of the patent laws. Usefulness in patent law, and in particular in the context of pharmaceutical inventions, necessarily includes the expectation of further research and development. The stage at which an invention in this field becomes useful is well before it is ready to be administered to humans. Were we to require Phase II testing in order to prove utility, the associated costs would prevent many companies from obtaining patent protection on promising new inventions, thereby eliminating an incentive to pursue, through research and development, potential cures in many crucial areas such as the treatment of cancer.

Brana at 1442-1443, citations omitted. In assessing the question of whether undue experimentation would be required in order to practice the claimed invention, the key term is "undue", not "experimentation". *In re Angstadt and Griffin*, 190 USPQ 214 (C.C.P.A. 1976). The need for some experimentation does not render the claimed invention unpatentable. Indeed, a considerable amount of experimentation may be permissible if such experimentation is routinely practiced in the art. *In re Angstadt and Griffin, supra*; *Amgen, Inc. v. Chugai Pharmaceutical Co., Ltd.*, 18 USPQ2d 1016 (Fed. Cir. 1991). As a matter of law, it is well settled that a patent need not disclose what is well known in the art. *In re Wands*, 8 USPQ 2d 1400 (Fed. Cir. 1988).

The Examiner alleges that Claim 4 is drawn to polynucleotides encoding proteins of unidentified function. The Examiner's rejection is respectfully traversed. Claim 4 clearly states "An isolated nucleic acid molecule comprising the nucleotide sequence of a novel human kinase described in SEQ ID NO: 1. " (Emphasis added.) In addition, it is stated throughout the specification, beginning with the title, continuing with the subject of the background and emphasized through out the specification (for example, page 2, line 4 and page 15, line, 21-25). The invention is clearly a novel human kinase that shares sequence similarity with other animal kinases, especially serine/theronine protein kinases. It is clear that one of ordinary skill in the art would recognize the invention as a kinase and that the utility of such a kinase, being well established and substantial would also be recognized by one of skill in the art. Kinases are well known to those of skill in the art to catalyze phosphorylation. These reactions play a critical role in, *intra alia*, energy transfer, signal transduction and cell activation. Thus a kinase, such as the novel human kinase described and claimed in this application, has well established and substantial utility. Additionally, more than a hundred U.S. Patents having been issued on kinases and as previously stated U.S. Patent No. 5,817,479 (which is incorporated by reference in the present application) was issued on a group of Human Kinase Homologs. U.S. Patent No. 5,817,479 discloses a series of polynucleotide fragments from various human kinases. Applicants reiterate that issued U.S. Patents are presumed to meet the requirements of 35 U.S.C. sections 101, 102, 103 and 112, specifically, that they have utility, are novel, non-obvious, are enabled, meet the written description requirements and particularly point out and distinctly claim the invention. Thus, Applicants have rebutted the Examiner's prima

facia allegation that the present invention lacks utility with an overwhelming body of evidence supporting the well recognized utility of kinases from both the scientific community (*i.e.*, those skilled in the art) *and* the U.S. Patent and Trademark Office as well. Given the clear evidence of the utility of kinases, Applicants respectfully submit that in order to legally support and maintain the utility rejection, the Examiner now bears the burden of providing evidence to the record that specifically refutes the utility of the presently claimed kinase at issue. Absent such direct and specific evidence, the utility rejection is legally improper and should be withdrawn.

The Applicants would also like to invite the Examiner's attention to U.S. Patent No. 5,817,479 which discloses a series of polynucleotide fragments from human kinases. Applicants reiterate that issued U.S. Patents are presumed to meet the requirements of 35 U.S.C. sections 101, 102, 103 and 112, specifically, that they have utility, are novel, non-obvious, are enabled, meet the written description requirements and particularly point out and distinctly claim the invention. The issuance of U.S. Patent 5,817,479 indicates that the patented kinase fragments have specific and substantial utility . Scientific and legal logic demands that if sequence fragments of human kinases have utility, then *full length* human kinases, which clearly have more scientific and practical utility than kinase fragments, must also have a patentable utility. In addition, since U.S. Patent 5,817,479 is presumed to teach a specific and substantial utility for human kinase fragments *and* given that the disclosure of U.S. Patent 5,817,479 has been bodily incorporated by reference into the present application (page 15, line 28), it is axiomatic that the present application must also teach a substantial and specific utility for human kinase fragments as well as a *full length*

human kinase. Any conclusion to the contrary is not supported by any evidence presently of record, and would not be consistent with established U.S. Patent and Trademark Office procedures and policies. Accordingly, Applicants respectfully submit that the present specification, which describes an entire novel human kinase, describes a utility fully compliant with the provision of 35 U.S.C. section 101.

Applicants therefore respectfully request that the rejection of claim 4 under 35 U.S.C. § 101, be withdrawn.

III. Rejection of Claim 4 Under 35 U.S.C. § 112, First Paragraph

The Action next rejects Claim 4 under 35 U.S.C. § 112, first paragraph, since allegedly one skilled in the art would not know how to use the invention, as the invention allegedly is not supported by a specific, substantial, and credible utility or a well-established utility. Applicants respectfully traverse.

Applicants submit that one of ordinary skill in the art would recognize the invention as a kinase and that the utility of such a kinase would also be readily recognized by one of skill in the art as kinases, their utility and their uses as well as methods for the same are well known to those of skill in the art.

Additionally, Applicants submit that as claim 4 has been shown to have "a specific, substantial, and credible utility", as detailed in section II above, the present rejection of claim 4 under 35 U.S.C. § 112, first paragraph, cannot stand.

Applicants therefore request that the rejection of claim 4 under 35 U.S.C. § 112, first paragraph, be withdrawn.

IV. Rejecti n of Claims 1-3 Under 35 U.S.C. § 101

Claims 1-3 remain rejected under 35 U.S.C. section 101, because the claimed invention lacks patentable utility. Applicants respectfully traverse.

First, while Applicants in no way agree with the Examiner's position that one skilled in the art would not know how to use the invention as set forth in claim 1, since claim 1 has been cancelled entirely without prejudice and without disclaimer solely in order to more rapidly progress the present case to allowance, the present rejection of claim 1 under 35 U.S.C. § 101 is rendered moot. The remainder of this section will therefore focus on claims 2 and 3.

The Action persists in the remarkable assertion that the invention claims polynucleotides and proteins of unidentified function. This in spite of statements throughout the specification, beginning with the title, continuing with the subject of the background section, and reiterated throughout the specification (for example, page 2, line 4 and page 15, line, 21-25) that the invention is clearly a novel human kinase that shares a conclusively high sequence similarity with other kinases.

The Action argues that the rejection was based on the utility of the particular sequence and not the whole genus of novel human kinases or newly identified genomic sequences. Applicants respectfully disagree. The utility of any kinase would be readily recognized by one of skill in the art, as kinases, their utility, their uses and medical importance are very well known. Kinases catalyze the transfer of phosphates, a process known as phosphorylation. Phosphorylation is critical to cell processes *intra alia*, energy transfer, signal transduction and cell activation. Many oncogenes are kinases or kinase

linked receptors. Kinases are also well known to the art as targets for compounds that inhibit cellular signaling and regulation. Many highly successful and highly profitable drug therapies for cancer and as antivirals are directed at kinases. Thus kinases, their utility, uses and value are well established and readily recognizable by those of skill in the art.

Furthermore, there are more than a hundred issued U.S. Patents on kinases and in addition there are many issued U.S. Patents on kinase inhibitors, the utility of such being so well established. Thus any kinase, such as the novel human kinase described and claimed in this application, has well established and substantial utility. More than a hundred U.S. Patents having been issued on kinases and as previously stated U.S. Patent No. 5,817,479 was issued on a group of Human Kinase Homologs. U.S. Patent No. 5,817,479 discloses a series of polynucleotide fragments from human kinases. Applicants reiterate that issued U.S. Patents are presumed to meet the requirements of 35 U.S.C. sections 101, 102, 103 and 112, specifically, that they have utility, are novel, non-obvious, are enabled, meet the written description requirements and particularly point out and distinctly claim the invention. Thus, Applicants have answered the Examiner's *prima fascia* case with an overwhelming body of evidence as to the patentability and well recognized utility of kinases, not only from the scientific community but from the U.S. Patent and Trademark Office as well. Applicant therefore invites the Examiner to provide direct evidence refuting this body of evidence.

In addition, issued U.S. Patent No. 5,817,479 discloses a series of polynucleotide fragments from human kinases. Applicants reiterate that issued U.S. Patents are presumed to meet the requirements of 35 U.S.C. sections 101, 102, 103 and 112,

specifically, that they have utility, are novel, non-obvious, are enabled, meet the written description requirements and particularly point out and distinctly claim the invention. The issuance of U.S. Patent 5,817,479 indicates that the patented kinase fragments have specific and substantial utility . Scientific and legal logic demands that if sequence fragments of human kinases have utility, then *full length* human kinases, which clearly have more scientific and practical utility than kinase fragments, must also have a patentable utility. In addition, since U.S. Patent 5,817,479 is presumed to teach a specific and substantial utility for human kinase fragments and this issued U.S. Patent 5,817,479 has been bodily incorporated by reference into the present application (page 15, line 28), logically the present application also teaches substantial and specific utility for human kinase fragments including a *full length* human kinase Any other conclusion would not be consistent with established U.S. Patent and Trademark Office procedures and policies. In light of the issuance of numerous U.S. Patents on kinases and fragments thereof (for example U.S. Patent No. 5,817,479), the U.S. Patent and Trademark Office has already acknowledged that those skilled in the art would believe that kinases proteins disclosed and claimed as in the present application have a patentable utility. Applicants respectfully submit that the present specification, which describes a *full length* novel human kinase, describes a utility fully compliant with the provision of 35 U.S.C. section 101.

Applicants therefore respectfully request that the rejection of claims 2 and 3 under 35 U.S.C. § 101, be withdrawn.

V. Rejection of Claim 1-3 Under 35 U.S.C. § 112, First Paragraph

The Action next rejects claims 1-3 under 35 U.S.C. § 112, first paragraph, since allegedly one skilled in the art would not know how to use the invention, as the invention allegedly is not supported by a specific, substantial, and credible utility or a well-established utility. Applicants respectfully traverse.

First, while Applicants in no way agree with the Examiner's position that one skilled in the art would not know how to use the invention as set forth in claim 1, since claim 1 has been cancelled entirely without prejudice and without disclaimer solely in order to more rapidly progress the present case to allowance, the present rejection of claim 1 under 35 U.S.C. § 112, first paragraph is rendered moot. The remainder of this section will therefore focus on claims 2 and 3.

Applicants submit that one of ordinary skill in the art would recognize the invention as a kinase and that the utility of such a kinase would also be readily recognized by one of skill in the art as kinases, their utility and their uses as well as methods for the same are well known to those of skill in the art.

Additionally, Applicants submit that as claims 2 and 3 have been shown to have "a specific, substantial, and credible utility", as detailed in section IV above, the present rejection of claims 2 and 3 under 35 U.S.C. § 112, first paragraph, cannot stand.

Applicants therefore request that the rejection of claims 2 and 3 under 35 U.S.C. § 112, first paragraph, be withdrawn.

VI. Rejection of Claim 2 Under 35 U.S.C. § 112, Second Paragraph

The Action next rejects claim 2 under 35 U.S.C. § 112, second paragraph, as being allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention. Applicants respectfully traverse.

The Action recognizes that Applicants have amended claim 2 to specify highly stringent conditions, but indicates that the highly stringent condition defined on page 4, lines 17-29 is only one description of highly stringent conditions and therefore those that apply to claim 2 are unclear.

The Action acknowledges that different nucleic acids hybridize to a DNA sequence under different conditions. One of the main differences that can effect hybridization conditions is the length of the nucleotides. It is well known to those skilled in the art that hybridization conditions for oligonucleotides is distinct from hybridization conditions used for longer polynucleotides such as the full length kinase encoding sequences of the presently claimed invention. That is precisely why highly stringent conditions are separately defined for both oligonucleotides and for larger polynucleotides in the specification.

The term "highly stringent" is defined in two locations in the specification. First on page 4, lines 15-23, where the specification refers to larger polynucleotide sequences:

"that hybridizes to a complement of a DNA sequence presented in the Sequence Listing under highly stringent conditions, e.g., hybridization to filter-bound DNA in 0.5 M $NaHPO_4$, 7% sodium dodecyl sulfate (SDS), 1 mM EDTA at 65°C, and washing in 0.1xSSC/0.1% SDS at 68°C (Ausubel F.M. et al., eds., 1989, Current Protocols in Molecular Biology, Vol. I, Green Publishing Associates, Inc., and John Wiley & sons, Inc., New York, at p. 2.10.3)".

Finally on page 6, lines 13-17 where highly stringent conditions are defined for hybridizations involving oligonucleotide probes:

"For oligonucleotide probes, highly stringent conditions may refer, e.g., to washing in 6xSSC/0.05% sodium pyrophosphate at 37°C (for 14-base oligos), 48°C (for 17-base oligos), 55°C (for 20-base oligos), and 60°C (for 23-base oligos). "

Since it is well know by those skilled in the art that hybridization conditions for oligonucleotides are distinct from those for the longer polynucleotides described in the presently pending claims, Applicants described highly stringent conditions for both oligonucleotides and larger polynucleotides in the specification. Clearly as claim 2 refers

to non-oligonucleotide hybridization "(b) hybridizes under highly stringent conditions to the nucleotide sequence of SEQ ID NO: 1 or the full complement thereof." - the highly stringent conditions defined on page 4, lines 15-23, are applicable. Applicants therefore request that the rejection of claim 2 under 35 U.S.C. § 112, second paragraph, be withdrawn.

VII. CONCLUSION

The present document is a full and complete response to the Action. In conclusion, the Applicants believe that In view of the foregoing amendments and remarks the application is in good and proper condition for allowance. Early notification to that effect is earnestly solicited.

If the Examiner feels that a telephone call would expedite the consideration of the application, the Examiner is invited to call the undersigned attorney at (281) 863-3333.

Respectfully submitted,

January 11, 2002
Date

Lance K. Ishimoto by [illegible] Fg 40,162
Lance K. Ishimoto Reg. No. 41,866

LEXICON GENETICS INCORPORATED
4000 Research Forest Drive
The Woodlands, TX 77381
(281) 863-3333